

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF TEXAS**

IN RE REPOS THERAPEUTICS, INC.  
SECURITIES LITIGATION

**Civil Action No. 09 Civ. 2530(VDG)**

**CONSOLIDATED CLASS ACTION COMPLAINT**

1. This is a securities class action against Repros and certain of its officers and/or directors for violations of the Securities Exchange Act of 1934 (“1934 Act”), on behalf of all persons who purchased common stock of Repros Therapeutics, Inc. (“Repos” or the “Company”) between July 1, 2009 and August 2, 2009 (the “Class Period”) and were injured thereby.

2. Defendant Repros is a pharmaceutical company that conducted clinical trials for its drug Proellex, which was designed to treat symptoms associated with uterine fibroids and endometriosis. On July 1, 2009, six months after the supposed conclusion of a Phase 2 trial for Proellex, during which Repros was receiving contemporaneous electronic results, Repros issued a press release reiterating the positive results of that trial, but noted that it was discontinuing further testing of the 50mg dose since there was no difference in efficacy between the 50mg and 25mg dose and there was an increase in liver enzymes in only the 50mg dose. However, this was just the tip of the iceberg. The elevation of liver enzymes was much more severe than Defendants let on in that press release. By August 3, 2009, less than five weeks after the July 1, 2009 press release, Defendants were forced to do an about-face, reveal the full extent of these problems, and announce the cancellation of all clinical trials for Proellex. During that time, the

price of Repros dropped over 73% from a close of \$4.96 on July 1, 2009 to a close of \$1.31 on August 3, 2009.

3. Repros had, and still has, serious financial problems, and has been flirting with insolvency for some time. As detailed below, during the Class Period Defendants were forced to raise significant capital very quickly; if the truth about Proellex was revealed in a timely manner, Defendants' fundraising efforts could have been jeopardized. Defendants feared that revealing the truth at that time about the elevated liver enzymes could essentially put the final nail in the coffin for Repros. To avoid this, and to maximize their chances of obtaining funding, Defendants issued misstatements during a five-week period about Proellex that had no basis in fact and deliberately or recklessly concealed the truth regarding the severity of the safety issues.

### **JURISDICTION AND VENUE**

4. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. Section 78j(b) and Section 78t(a), and Rule 10b-5, 17 C.F.R. Section 240 10b-5, promulgated thereunder by the SEC.

5. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Repros's principal executive office is located in this District.

6. In connection with the acts, conduct and other wrongs alleged in this Complaint, the Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the mails, telephone communications and the facilities of national securities exchanges.

### **PARTIES**

7. Court-appointed lead plaintiff Raymond Wong purchased common stock of

Repos during the Class Period.

8. Plaintiff Jim Chen purchased common stock of Repos during the Class Period.

9. Defendant Repos Therapeutics, Inc., develops “oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.” Repos’s principal executive offices are located at 2408 Timberloch Place, Woodlands, Texas.

10. Defendant Joseph Podolski served as Repos’s Chief Executive Officer and a director during the Class Period. Defendant Podolski also became Repos’s President on or around October 29, 2009.

11. Defendant Paul Lammers served as Repos’s President from February 2009 until his resignation on or around October 29, 2009. After Defendant Lammers was hired, he stated in a February 23, 2009 press release issued via BUSINESS WIRE that “I look forward to the challenge of bringing Proellex to the market and developing Repos into a world class commercial biotechnology company.” Defendant Lammers was listed as a contact person on all of the press releases alleged to be misleading.

12. Defendant Louis Ploth, Jr. served as Repos’s Chief Financial Officer and a director during the Class Period. On September 16, 2009, Ploth was removed from his position as Chief Financial Officer. Defendant Ploth signed each Form 8-K containing the press releases alleged to be misleading.

13. Defendants Podolski, Lammers, and Ploth are referred to collectively as the “Individual Defendants.”

14. Each of the Individual Defendants had a key position with the Company, and had firsthand knowledge of the relevant issues surrounding Proellex. Proellex was Repos’s key product, and the safety of Proellex was crucial to the survival of the Company. Given that

Repos had only ten employees, and the Individual Defendants were top management of this small company, each of the Individual Defendants knew of key events impacting the health of the company, including negative results of the clinical trials. In fact, Repos's Form 10-K for year-end 2008, filed with the SEC on or around March 16, 2009 ("2008 10-K") noted that "[w]e are highly dependent on Messrs. Podolski and Ploth and [Dr.] Lammers . . . for the management of our company and the development of our technologies."

### **CLASS ACTION ALLEGATIONS**

15. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a Class, consisting of all persons who purchased or otherwise acquired Repos common stock between July 1, 2009 and August 2, 2009, inclusive, and who were damaged thereby. Excluded from the Class are Defendants, members of the immediate family of any Individual Defendant, any subsidiary or affiliate of Repos and the directors, officers and employees of Repos or its subsidiaries or affiliates, or any entity in which any excluded person has a controlling interest, and the legal representatives, heirs, successors, and assigns of any excluded person.

16. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are hundreds if not thousands of members of the Class located throughout the United States. As of March 6, 2009, there were over 15 million shares of Repos common stock outstanding. Throughout the Class Period, Repos common stock was actively traded on the NASDAQ (an open and efficient market) under the symbol "RPRX." Record owners and other members of the Class may be identified from records maintained by Repos and/or its transfer agents and may be

notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

17. Lead Plaintiff's claims are typical of the claims of other members of the Class as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of the federal law that is complained of herein.

18. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

19. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a. whether the 1934 Act was violated by Defendants;
- b. whether Defendants omitted and/or misrepresented material facts;
- c. whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- d. whether Defendants knew or deliberately disregarded that their statements were false and misleading;
- e. whether the misstatements caused stockholders' loss; and
- f. the extent of damage sustained by Class members and the appropriate measure of damages.

20. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and

burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

21. Repros stock traded in an efficient market during the Class Period, as is evidenced by the following factors:

a. The reported trading volume of Repros common stock during the Class period was 4,227,000 shares, or a weekly average of 845,000 shares. Based on the over 15 million shares of Repros common stock outstanding as of August 14, 2009, the average weekly turnover of Repros common stock during the Class Period was 5.6%.

b. During the Class Period, analysts from at least six investment banking firms issued reports on Repros.

c. During the Class Period, there were sixteen market makers that actively traded Repros common stock.

d. During the Class Period, Repros was eligible to file a Form S-3 Registration Statement with the SEC. Repros filed Forms S-3 both before and after the Class Period.

e. Repros's market capitalization during the Class Period fluctuated between \$35-75 million.

f. The average quoted closing bid-ask spread for Repros common stock during the Class Period was \$0.021 per share. Measured as a percent of the midpoint of the closing bid and ask prices, the average quoted closing bid-ask spread for Repros common stock during the Class Period was 0.52%.

g. As detailed below, news issued by the Company caused the stock price to fluctuate.

### **SUBSTANTIVE ALLEGATIONS**

#### **A. Repros and Proellex**

22. Repros is a “development stage biopharmaceutical company” that develops “oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.”

23. Repros has two key products in its pipeline, Proellex and Androxal. Its main product Proellex was developed to treat three medical problems: (1) anemia associated with uterine fibroids; (2) treatment of chronic symptoms associated with uterine fibroids; and (3) treatment of chronic symptoms associated with endometriosis. Prospects regarding Androxal were much dimmer; Repros has stated that it “do[es] not have a clear clinical path to develop Androxal” in the United States, and its only promise is in the “limited European market.”

24. Repros stated in its 2008 10-K that its primary business strategy was “to concentrate our resources on the clinical development of Proellex for uterine fibroids, anemia associated with uterine fibroids and endometriosis in order to achieve commercialization as soon as practicable. In addition, we are accumulating safety results for all three Proellex indications in order to expedite the development of Proellex.”

25. Proellex was not invented by Repros. Starting in 1999, Repros licensed Proellex from the National Institute of Health (“NIH”), in accordance with a license agreement that has been amended over time. The license agreement gives Repros the rights to develop Proellex, and in turn, Repros must pay the NIH a licensing fee and must meet various milestones for the commercial development of Proellex, including eventual approval by the FDA. If these

milestones are not met, the NIH could revoke the licensing agreement, causing Repros to lose its key product.

**B. Proellex's Clinical Trials**

26. On March 16, 2009, before the start of the Class Period, Defendants announced in the 2008 10-K that they were conducting three clinical trials on Proellex. Two trials on patients with symptoms associated with uterine fibroids and anemia associated with uterine fibroids had completed the "Phase 2" stage and proceeded to the more advanced "Phase 3" stage. The other trial on patients with symptoms associated with endometriosis had completed the "Phase 2" stage in January 2009. Thus, by the start of the Class Period, each of the three clinical trials had completed the Phase 2 stage.

27. According to clinicaltrials.gov, a website maintained by the National Institute of Health, Phase 1 trials are "[i]nitial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients." Phase 2 trials are "[c]ontrolled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks." Phase 3 trials are "[e]xpanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling." Phase 4 trials are "[p]ost-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use."

28. Thus, Phase 1 and 2 trials are focused on the side effects and risks, while the



Phase 3 and 4 trials are focused on the benefit-risk relationship. In conducting the trials, Repros gathered its patient data from an “electronic data capture” system, so results obtained from blood tests could be analyzed by Repros almost instantaneously.

29. As a primary purpose of a Phase 2 trial is to determine side-effects and risks, upon the conclusion of the respective Phase 2 trials on Proellex, Repros investors believed that any major toxicity problems would have been revealed, and Proellex was “over the hump” regarding these issues.

30. Repros explained, in its 2008 10-K, that the Phase 2 trial for endometriosis, internally referred to as ZPE-201, “tested two doses of Proellex, 25mg and 50mg, as a once-a-day oral therapy versus placebo in a double-blind design and was four-months in duration.” After this four-month period, “patients will roll over to an Open Label Safety Extension Study (ZPE-201 ext) on Proellex 25 mg with the option to up-titrate to 50 mg if symptoms are not adequately controlled. This extension study will allow these completed patients to be treated for two additional four-month cycles with an intervening menstruation between each cycle if symptoms recur.” Accordingly, at the conclusion of this Phase 2 trial, Repros should have had a complete set of data regarding any adverse health effects, including elevated liver enzymes. In fact, Defendants noted in the 2008 10-K that “[t]here was a clear dose response in the Proellex treatment groups, and Proellex was well tolerated over the course of the trial.”

31. Defendants Podolski and Lammers each played a key role in the management of Proellex’s clinical trials. Lammers was hired in February 2009 to guide Repros through the regulatory process in bringing Proellex to market. Furthermore, both Podolski and Lammers had firsthand knowledge of the status of the clinical trials and Proellex’s effect on patients. On March 16, 2009, both Podolski and Lammers participated in a year-end earnings conference call,

where they both discussed, in detail, the results of the Proellex clinical trials.

**C. Repos's Financial Health Was Dependent on The Success of Proellex**

32. By the middle of 2009, Repos's financial viability was tenuous at best. Repos stated in its 2008 10-K that "[w]e expect our current capital to be sufficient to fund our operations through at least the second quarter of 2009, depending on the timing and success of our clinical trials. Thereafter, we will need to seek additional funding through public or private financings, including equity and debt financings, and/or through other means, including collaborations and licensing agreements."

33. Furthermore, the NIH was aware of Repos's precarious financial situation, and pressured Repos to obtain additional funding. After negotiations, on July 7, 2009, Repos and the NIH entered into the sixth amendment to the Licensing Agreement. Various milestones were extended, but the amended agreement provided that, by September 30, 2009, Repos must "[o]btain financing, upfront licensing consideration, or any combination thereof . . . of no less than a combined total of Six Million Dollars (\$6,000,000)."

34. Because Repos was running out of capital, and had a deadline from the NIH, it would need to attract additional investment during the third quarter of 2009 in order to survive, even in the short term. If Repos issued negative news on Proellex, any possibility of additional investment could be jeopardized.

35. In fact, Defendants admitted that any delay in the commercial development of Proellex could doom the Company. Repos stated in its 2008 10-K that "[i]f we delay or abandon our development efforts related to Proellex or Androxal, we may not be able to generate sufficient revenues to continue operations or become profitable."

36. By January 2009, before the start of the Class Period, Repros had concluded its Phase 2 clinical trial for use of Proellex in the treatment of endometriosis. According to a press release issued on January 12, 2009 via BUSINESS WIRE, Repros noted “statistically significant reductions” in the endometriosis symptoms of participants in the trial. Repros’s 2008 10-K, filed on March 16, 2009, stated that “[w]e are preparing to request an end of Phase 2 meeting with the FDA that we anticipate could occur mid-year 2009. Pending positive FDA outcome from that meeting and acceptance of clinical protocols, we plan to initiate registration Phase 3 pivotal trials as soon as practicable. We estimate the filing of a NDA [New Drug Application] for endometriosis in late 2010-2011.”

37. To maximize the chance of obtaining the additional financing needed to save Repros, on July 1, 2009, Defendants began a campaign to conceal or minimize negative news about Proellex. Given that Defendants had to reverse their position a mere five weeks later, a full seven months after the conclusion of the Phase 2 trial related to the treatment of endometriosis, Defendants either (1) knew Proellex had a negative impact on elevated liver enzymes that undermined its safety, and deliberately issued press releases that concealed such information from investors; or (2) did not have sufficient evidence on the safety of Proellex, but, in an extreme departure from the standards of ordinary care, recklessly issued press releases that minimized the safety concerns for Proellex. This approach could provide Repros with a stay of execution and could buy Defendants some additional time to deal with the funding issues.

**D. Repros’s Misstatements Regarding Proellex**

38. On July 1, 2009, the beginning of the Class Period, Repros announced an update to the supposed results of the Phase 2 trial, and issued a press release over BUSINESS WIRE stating as follows:

The Phase 2 study that Repros completed earlier this year demonstrated clinically and statistically significant reductions of the three key pain symptoms commonly experienced by women with endometriosis: dysmenorrhea (painful menses), non-menstrual pelvic pain, and dyspareunia (painful intercourse). Additionally, the reduction of pain was accompanied by a statistically significant reduction in the number of patients requiring pain medication in both doses in this Phase 2 study compared with placebo. The study showed no efficacy differences between the 25 mg and 50 mg doses.

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Furthermore, Repros has decided to discontinue the use of the higher, 50 mg dose in its ongoing studies in women with chronic symptomatic uterine fibroids and anemia associated with this condition due to an observed dose-dependent increase in liver enzymes in a low percentage of women. To date, Repros has dosed over 600 patients, and over 200 patients have completed at least one dosing period followed by an off-drug interval. From completed studies as well as from the ongoing large open label trial, it has been determined that the drug is well tolerated with few women discontinuing treatment due to adverse events.

Repros believes that the decision to discontinue the higher dose will most likely improve the benefit/risk profile of the drug. To date, there has been no evidence for an increase in efficacy at the 50 mg dose. In addition, earlier studies have demonstrated highly effective control of excessive menstrual bleeding and clinically significant improvement in quality of life parameters at the lower doses of 12.5 and 25 mg.

To further support the efficacy of the lower doses of Proellex, Repros will also initiate additional placebo-controlled studies with the 12.5 mg dose to supplement the overall efficacy and safety profile of the drug in these important indications. Repros does not expect that these additional studies will adversely affect the timing of its regulatory submissions and remains committed to its target date for filing NDAs for the uterine fibroids indications in the second half of 2010.

39. This press release listed Defendant Lammers as a contact person. It was submitted to the SEC via a Form 8-K, dated July 2, 2009, which was signed by Defendant Plath.

40. The above press release contained the following material misrepresentations and/or omissions:

- a. it falsely stated that Proellex is “well tolerated”;

b. it failed to reveal that the issues regarding elevated liver enzymes were so severe that they could lead to the cancellation of all of the Proellex trials; and

c. it failed to reveal that Defendants issued news on Proellex's safety that had no reasonable basis in fact, with intentional or reckless disregard for the truth, because they did not want to jeopardize their attempts to obtain the immediate additional funding needed to meet both Repros's capital requirements and the September 30, 2009 NIH financing deadline.

41. Repros's stock price dropped on this news because investors were disappointed by the discontinuance of the 50mg dose of Proellex. While Repros mentioned that there was an increase in liver enzymes for patients taking the 50mg dose, the press release included no discussion of any adverse health issues arising from such an increase, and stated that the 50 mg dose was also discontinued because there was a lack of an "increase in efficacy" for that dose. While that day the stock price dropped from \$7.19 the day before to close at \$4.96, had investors known that there were significant problems with elevated liver enzymes at all three dosing levels that would jeopardize all of Proellex's clinical trials, the stock price would have dropped even further, as it did when the truth was finally revealed.

42. On July 7, 2009, Repros issued a press release over BUSINESS WIRE stating as follows:

The Woodlands, Texas — July 7, 2009, Repros Therapeutics (NasdaqGM:RPRX) provides a further update on the clinical development of Proellex 25 and 12.5 mg doses.

Repros' recent decision to discontinue the use of the Proellex 50 mg dose in its ongoing clinical studies was based on observations of a dose-related increase in liver enzymes in a low percentage of women. The company believes that the 25

mg and 12.5 mg doses will offer comparable efficacy benefits while providing an improved safety profile.

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Completed studies at 25 and 12.5 mg doses have demonstrated statistically and clinically significant control of excessive menstrual bleeding and improvement in quality of life parameters. In a completed Phase 2 study, which included 127 women with uterine fibroids, doses of 25 and 12.5 mg were compared to placebo for a period of three months. Both the 25 and 12.5 mg doses showed statistically significant ( $p < 0.0001$ ) improvements in three clinically relevant endpoints: hemoglobin level, menstrual bleeding scores and quality of life parameters.

Repos believes that the decision to move forward with the 25 and 12.5 mg doses will improve the benefit/risk profile of Proellex. Additionally, Repos believes that any new studies required for the approval of the 12.5 mg dose will not adversely impact anticipated timing of NDAs for Proellex.

43. On that day, the stock price rose to close at \$4.56, up from a close of \$4.24 the day before.

44. This press release listed Defendant Lammers as a contact person. It was submitted to the SEC via a Form 8-K, dated July 8, 2009, which was signed by Defendant Ploth.

45. The above press release contained the following material misrepresentations and/or omissions:

a. it falsely stated Repos had a reasonable basis to believe that “the 25 mg and 12.5 mg doses will offer comparable efficacy benefits while providing an improved safety profile”;

b. it failed to reveal that the issues regarding elevated liver enzymes were so severe that they could lead to the cancellation of all of the Proellex trials; and

c. it failed to reveal that Defendants issued news on Proellex’s safety that had no reasonable basis in fact, with intentional or reckless disregard for the

truth, because they did not want to jeopardize their attempts to obtain the immediate additional funding needed to meet both Repros's capital requirements and the September 30, 2009 NIH financing deadline.

**E. The Truth is Revealed**

46. On July 23, 2009, the truth about Proellex was partially revealed when Repros issued a press release over BUSINESS WIRE stating as follows:

Repros' recent decision to discontinue the use of the Proellex 50 mg dose in its ongoing clinical trials was based on observations of dose-related, clinically significant changes in liver enzymes ( $\geq 3 \times$  Upper Limit of Normal, or ULN) in a low percentage of women. Following this decision, Repros notified all clinical sites involved in the studies of this important change, and all patients on the 50 mg dose have been switched to a 25 mg dose.

All subjects with liver enzyme elevations  $\geq 3 \times$ ULN had their treatment stopped and have been referred to an appropriate specialist for further evaluation. Of the nine subjects identified in the Press Release of July 7, 2009, with liver enzymes  $\geq 3 \times$ ULN on the 50 mg dose, the majority have had a reduction of their serum liver enzymes to within the normal range. Four of these subjects have not yet resolved and they are being followed closely. To date, no patient with elevated liver enzymes has required any type of additional treatment for this condition. All subjects in all ongoing trials are being monitored frequently to detect any type of change in liver enzyme levels.

As stated previously, Repros believes that the decision to move forward with the 25 mg and 12.5 mg doses will improve the benefit/risk profile of Proellex. The Company informed the Food and Drug Administration, or FDA, of the decision to discontinue the 50 mg dose on June 26, 2009, and intends to obtain guidance from the FDA in the coming months on the clinical and regulatory pathways forward for the Proellex clinical programs.

47. This press release listed Defendant Lammers as a contact person. It was submitted to the SEC via a Form 8-K, dated July 23, 2009, which was signed by Defendant Ploth.

48. Although information regarding elevated liver enzymes was partially revealed, the above press release contained the following material misrepresentations and/or omissions:

a. it failed to reveal that the issues regarding elevated liver enzymes were so severe that they could lead to the cancellation of all of the Proellex trials; and

b. it failed to reveal that Defendants issued news on Proellex's safety that had no reasonable basis in fact, with intentional or reckless disregard for the truth, because they did not want to jeopardize their attempts to obtain the immediate additional funding needed to meet both Repros's capital requirements and the September 30, 2009 NIH financing deadline.

49. On July 23, 2009, the stock closed at \$2.99, a 39% drop from a close \$4.92 the day before.

50. However, by the end of July, the Defendants realized that they could no longer conceal all the information regarding elevated liver enzymes. They would be forced to reveal to the FDA the problems regarding elevated liver enzymes, and in turn they knew such information would be made public.

51. On August 3, 2009, before the market opened, and fewer than five weeks after Repros issued its press release minimizing the negative results of the Phase II trial for patients with endometriosis, Repros issued a press release over BUSINESS WIRE announcing the suspension of all Proellex clinical trials, based in a clinically significant increase in liver enzymes among participants:

The Woodlands, Texas —August 3, 2009, Repros Therapeutics (NasdaqGM:RPRX) announced today that, in the interest of patient safety, it is voluntarily suspending dosing of all patients in its clinical trials of Proellex. This decision is based on available information regarding the occurrence of clinically significant increases in liver enzymes with 50 mg and 25 mg doses of Proellex, coupled with recent input from a consulting panel of liver experts. The Company submitted a meeting request to the Food and Drug Administration (FDA) on July 30, 2009 and in response, FDA has proposed to change the topic of the previously



scheduled End of Phase 2 meeting for endometriosis in late September into a discussion about the safety of Proellex and overall direction and scope of the program.

#### Suspension of Clinical Trials

The suspension of dosing will involve all ongoing clinical trials with Proellex for the treatment of chronic symptomatic uterine fibroids, anemia associated with this condition, and endometriosis. All of the patients in these trials were receiving a dose of 25 mg per day. Previously, Repros informed the clinical research organizations (CROs) running the clinical trials to switch all patients who had been receiving 50 mg per day in the ongoing clinical trials to the 25 mg dose. The 12.5 mg dose had been previously studied in earlier Phase 2 uterine fibroid and endometriosis trials, but no patients were receiving 12.5 mg per day in any trial at the time dosing was discontinued.

#### Elevation of Liver Enzymes

The data presented below has been acquired from unlocked, unaudited clinical trial databases which are being updated as new information becomes available from patients treated with Proellex or Placebo, and from recent lab tests.

As of July 27, 2009, the following estimates existed:

- More than 600 patients participated in double blind and open label clinical trials with exposure to Placebo, or various doses of Proellex for more than 1 month.
- Of these, approximately 500 received Proellex (approximately 190 had received a dose of 50 mg per day; approximately 260 received a dose of 25 mg per day; 55 received a dose of 12.5 mg per day) and approximately 130 received Placebo.
- Thirteen (13) subjects had an increase in liver enzymes greater than three times the upper limit of normal ( $>3\times\text{ULN}$ ), all on Proellex, but in only 9 subjects was the increase in liver enzymes of  $>3\times\text{ULN}$  confirmed by a repeat test in 48 hours as recommended in FDA's Guidance\*. Each of these subjects either has been or is being followed closely with frequent monitoring of liver enzyme levels until the measurements return to baseline or normal or a decision is made by a consulting liver specialist that additional treatment is advisable.
- Of the 9 subjects with a confirmed increase in liver enzymes of  $>3\times\text{ULN}$ , 5 still had elevated enzymes as of July 27, 2009. These 5 patients had previously been dosed with the 50 mg dose. One of the 5 subjects was referred to a liver specialty clinic and was put on oral medication for treatment of her liver condition on July 26th. The Company was notified of this change in status on July 28th.

- Of the 9 subjects who had an increase in liver enzymes of >3xULN, 7 were severe enough elevations to be reported to the FDA as Serious Adverse Events (SAEs) (1 at a dose of 25 mg per day; 6 at a dose of 50 mg per day).

#### Financial Situation

Repros also announced that it is considering various financing alternatives to address its immediate short term liquidity needs. No assurance can be given that the Company will be successful in obtaining financing on acceptable terms or at all. The Company anticipates that if it is able to secure financing, that such financing will result in significant dilution of the ownership interests of its current stockholders and may provide certain rights to the new investors senior to the rights of its current stockholders, including but not limited to voting rights and rights to proceeds in the event of a sale or liquidation of the Company. In the event that the Company is unable to obtain adequate financing to meet its immediate short term liquidity needs, it will pursue other options, including but not limited to, reductions of expenses, sale of the Company, sale or license of a portion or all of its assets, a bankruptcy filing or the liquidation of the Company.

52. This press release listed Defendants Podolski and Lammers as contact persons. It was submitted to the SEC via a Form 8-K, dated August 3, 2009, which was signed by Defendant Plath.

53. On August 3, 2009, the stock closed at \$1.31, a 48% drop from a close of \$2.53 the trading day before. Overall, this was a 73% drop from the close of \$4.96 on July 1, 2009.

#### **F. Post-Class Period Developments**

54. On August 6, 2009, Repros was forced to reveal, in a press release over BUSINESS WIRE, that the FDA was placing Proellex on a clinical hold for safety reasons:

The Woodlands, Texas — August 6, 2009, Repros Therapeutics Inc. (NasdaqGM:RPRX) announced today that the Company received verbal notice on August 4, 2009 from the United States Food and Drug Administration (FDA) during a teleconference, requested by and held later that day with the Agency, that the Company's Investigational New Drug Applications (INDs) for Proellex have been placed on clinical hold for safety reasons. This action follows the Company's voluntary decision to suspend dosing of all patients in its clinical trials of Proellex (see press release dated August 3, 2009).

The Company and the FDA are scheduled to discuss the safety of Proellex and the overall direction and scope of the Company's clinical trials of Proellex at a meeting in late September. The FDA requested that the Company provide it with weekly updates about the patients who experienced a serious adverse event and still have elevated liver enzymes. The Company plans to provide such information as requested. In addition, at the September meeting Repros intends to present a detailed analysis of all of the patients with elevated liver enzymes, discuss the events that led to the suspension of the clinical trials, and determine whether and under which conditions, if any, the clinical hold may be lifted and the clinical trials of Proellex be safely resumed.

55. On September 16, 2009, Ploth was removed as Chief Financial Officer. As of October 29, 2009, Defendant Lammers resigned as President.

### **SCIENTER ALLEGATIONS**

56. As alleged herein, Defendants acted with scienter for the following reasons, all of which are at least as compelling as any competing inference:

a. Defendants knew or were reckless in not knowing that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading. Defendants knew such statements or documents would be issued or disseminated to the investing public, and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

b. The misstatements involved core operations of Repros, as they concerned the efficacy of Repros's key product.

c. The Individual Defendants had access to information regarding the misstatements, as Proellex had only approximately ten employees during that time. The Individual Defendants (who by themselves constituted 30% of Repros's workforce), by virtue of their receipt of information reflecting the true

facts regarding Repros, their control over, and/or receipt and/or modification of Repros's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Repros, participated in the fraudulent scheme alleged herein.

d. Each of the Individual Defendants knew or were reckless in not knowing of the falsity of the press releases at issue. Proellex was Repros's key product, and the safety of Proellex was crucial to the survival of the Company. Given that Repros had only ten employees, and the Individual Defendants were top management of this small company, each of the Individual Defendants knew of key events impacting the health of the company, including negative results of the clinical trials.

e. By January 2009, Proellex's three clinical trials had all completed the Phase 2 stage, and all of the relevant safety data had seemingly been analyzed. However, six months after the conclusion of this trial, Defendants began to make misstatements minimizing the safety concerns with Proellex. Merely five-weeks later they completely reversed their position on the safety of Proellex. Given the short five-week time period between the first misstatement and the revelation of the truth, it can be presumed that Defendants either (1) knew at the start of the Class Period that Proellex had a negative impact on elevated liver enzymes that undermined its safety, and deliberately concealed such information from investors; or (2) did not have sufficient evidence on the safety of Proellex, but, in an extreme departure from the standards of ordinary care, recklessly issued misstatements that had no basis in fact and minimized the safety concerns for

Proellex.

f. Defendants had a specific motive to issue the misrepresentations during a specific time frame, because revelation of the truth would have jeopardized efforts to obtain immediate funding, which Defendants needed in order to meet both Repros's capital requirements and the September 30, 2009 NIH financing deadline.

g. Defendants Ploth and Lammers both left the Company soon after the truth about Proellex's adverse health impact was revealed.

### COUNT I

#### **Pursuant to § 10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

57. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

58. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

59. Defendants violated § 10(b) of the 1934 Act and Rule 10b-5 in that they:

- a. employed devices, schemes and artifices to defraud;
- b. made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

c. engaged in acts, practices and a course of business that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of Repros common stock during the Class Period.

60. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Repros common stock. Lead Plaintiff and the Class would not have purchased Repros common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements. Moreover, at the end of the Class Period, the price of Repros dropped when the artificial inflation was removed from the stock price. As a result, investors during the Class Period could no longer recover the artificial inflation.

## **COUNT II**

### **Pursuant to § 20(a) of the 1934 Act Against The Individual Defendants**

61. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

62. Defendants Podolski, Lammers, and Ploth acted as controlling persons of Repros within the meaning of Section 20(a) of the 1934 Act as alleged herein. By virtue of their high-level positions, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Repros, including the content and dissemination of the various statements which Lead Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's press releases alleged by Lead Plaintiff to be misleading prior to and/or shortly

after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

63. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular statements giving rise to the securities violations as alleged herein, and exercised the same.

64. Furthermore, by engaging in the conduct alleged above, the Individual Defendants culpably participated in the fraud alleged above, directly and/or indirectly causing the investors' losses.

65. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the 1934 Act jointly and severally with Repros for Repros's violation of Section 10(b) and Rule 10b-5. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

#### **PRAYER FOR RELIEF**

WHEREFORE, Lead Plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding Lead Plaintiff and the other members of the Class damages, including interest;
- C. Awarding Lead Plaintiff and the other members of the Class reasonable costs and attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

Dated: January 27, 2010

**EMERSON POYNTER LLP**

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*Lead Counsel*



**CERTIFICATE OF SERVICE**

I hereby certify that on the 27<sup>th</sup> day of January, 2010, I electronically filed the Consolidated Complaint with the Clerk of the Court using the CM/ECF system, which shall send notification of such filing to all ECF participants in this case.

/s/ John G. Emerson  
John G. Emerson